Attachment F

ATTACHMENT F

(Retyped from Original Facsimile dated July 7, 2003)

2916 SW 98th Way
Gainesville, FL 32608
July 7, 2003

Mr. Robert Gelardi, President
The International Formula Council
5775G Peachtree-Dunwoody Road, Suite 500
Atlanta, GA 30342

Dear Bob:

I am writing you to present a summary of industry data submitted to me regarding testing for *Enterobacter sakazakii* in powdered infant formula. Presenting the data split for the two time periods reported, July 2002 to the end of February 2003, and March 1, 2003 to the end of June 2003 reflects how the data was sent to me, and also demonstrates a decrease in the occurrence of *E. sakazakii* over time. I have seen nothing to indicate that the data presented here are not representative of the maximum likely incidence of positives across the industry.

The first data presented below could be combined and summarized from four companies as results from 333-gram analytical units, the current FDA sample size in their testing matrix. Additionally significant data was submitted, but could not be directly compared to the 333-gram FDA sample size; that data appears under "Other Data."

July 2002 to February 28, 2003

2,442 analyses were conducted on 1,198 batches/lots of finished powdered infant formula. There were 36 positive findings for *E. sakazakii* (3.0% of batches).

March 1, 2003 to June 30, 2003

1,397 analyses were conducted on 521 batches/lots of finished powdered infant formula. There was 1 positive finding for *E. sakazakii* (0.19% of batches).

Given that the per month rates of testing for the two time periods are nearly identical, the data (even though from three and not four companies) strongly suggest a significant decrease in the finding of *E. sakazakii* in finished powdered infant formulas has been achieved.

Other Data

Other data submitted on 3,467 analyses conducted over three years, ending February 28, 2003 using a 100-gram analytical unit yielded a 1% rate of finding *E. sakazakii* on a per analysis basis, compared with a 1.47% positive finding rate on a per analysis basis (333-gram) for the time period July 2002 to February 28, 2003.

Sincerely,

Douglas L. Archer

Douglas L. Archer, Ph.D.